

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION**

**ALLIANCE FOR HIPPOCRATIC
MEDICINE**, on behalf of itself, its member
organizations, their members, and these
members' patients, *et al.*,

Plaintiffs,

v.

**U.S. FOOD AND DRUG
ADMINISTRATION**, et al.,

Defendants.

Case No. 2:22-cv-00223-Z

**PLAINTIFFS' BRIEF IN SUPPORT OF
CONSOLIDATING THE PRELIMINARY INJUNCTION HEARING
WITH A TRIAL ON THE MERITS UNDER RULE 65(A)(2)**

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INTRODUCTION

Plaintiff medical associations, doctors, and their patients have asked this Court to enter an order, while this case proceeds, to hold the FDA to its statutory duty to protect America's women and girls from the harms of dangerous chemical abortion drugs.

For two decades, the FDA has harmed women and girls by allowing dangerous chemical abortion drugs on the market and by failing to ensure even the most basic safeguards on their use. Without regard for federal law or sound medicine, the FDA has facilitated the creation of a mail-order and online abortion economy. This suit was brought by the local emergency room doctors, OB/GYNs, and other medical professionals who have cared for an increasing number of women seeking medical attention after taking this dangerous drug regimen. For two decades, these doctors have sought to protect their patients, navigating the FDA's byzantine administrative process to challenge the FDA's actions. The FDA has stonewalled Plaintiffs at every turn, imposing bureaucratic delay after bureaucratic delay—at one point, dragging its feet for over fourteen years—just so that the FDA could try to keep the doctors out of court and avoid judicial review of its actions.

It is now far past time for the FDA to be ordered to put politics aside, follow the law, and protect America's women and girls. The best way to do so is by promptly consolidating the preliminary injunction hearing with the trial on the merits under Rule 65(a). The Court should also order the swift production of the administrative record and expedite the case for trial. This course of action will and promote judicial efficiency by avoiding briefing the same legal issues in multiple rounds before the Court. And it will enable the Court resolve this case on the merits without prejudicing Plaintiffs and without introducing further delay—delay which will result in continued harm to women and girls.

BACKGROUND

For two decades, the FDA has failed America's women and girls by allowing chemical abortion drugs on the market and by failing to require minimum safeguards on their use. Complaint, ECF No. 1 at 1–2. Plaintiff medical associations, doctors, and their patients have thus asked this Court to enter injunctive and declaratory relief against the FDA, as well as to hold unlawful, vacate, and set aside each of the FDA's actions that approved chemical abortion drugs and that removed the safeguards on their use. *Id.* at 110–11.

Before the Court is the soon-to-be complete briefing on Plaintiffs' preliminary injunction motion. Plaintiffs immediately moved for a preliminary injunction to require the FDA to withdraw or suspend each of its actions while this case proceeds. ECF No. 6, 7. The FDA and Intervenor-Defendant Danco Laboratories have now filed their opposition briefs, ECF No. 19-1, 28; Plaintiffs' reply to the FDA's opposition is due today, February 10, 2023; and Plaintiffs' reply to Danco's opposition is due February 24, 2023. The Court has yet to schedule a hearing or oral argument on Plaintiff's preliminary injunction motion.

The Court ordered the parties to submit separate briefs on whether the Court should consolidate the injunction hearing and the trial on the merits under Federal Rule of Civil Procedure 65(a)(2). ECF No. 32.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 65(a), “[b]efore or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing.” This rule gives the district court “broad discretion in deciding whether to consolidate a preliminary injunction with the hearing of the motion for the permanent injunction.” *Sonnier v. Crain*, 613 F.3d 436, 442 (5th Cir. 2010), opinion withdrawn in part on reh’g on other grounds, 634

F.3d 778 (5th Cir. 2011). “The rule permits the Trial Judge to flexibly merge and hear the component parts of a case thereby avoiding repetition and unnecessary delay.” *Dillon v. Bay City Constr. Co.*, 512 F.2d 801, 804 (5th Cir. 1975).

Consolidation is appropriate so long as no party shows that consolidation will cause surprise or prejudice to the party. *Nationwide Amusements, Inc. v. Nattin*, 452 F.2d 651, 652 (5th Cir. 1971).

When a court consolidates a preliminary injunction hearing with the trial on the merits, courts hear oral argument on any legal questions and hold a bench trial on evidentiary issues to resolve any factual disputes. *See, e.g., Fath v. Tex. Dep’t of Transp.*, 924 F.3d 132, 136 (5th Cir. 2018) (per curiam) (bench trial in APA case). The court then will “find the facts specially and state its conclusions of law separately.” Fed. R. Civ. P. 52(a). The resulting hearing “really is a trial on the merits.” 11A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2950 (3d ed. Apr. 2022 update). If there are factual issues that could “reasonably be resolved in favor of either party,” then summary judgment is inappropriate, and “a finder of fact” must resolve them. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

ARGUMENT

This Court should expedite decision on this case and consolidate the preliminary injunction motion with a trial on the merits under Rule 65(a). It is far past time to order the FDA to rectify its lawless approval of mifepristone and to remove chemical abortion drugs from the market, or, at a minimum, to strengthen and restore safeguards on their use.

To resolve this case promptly, and to avoid undue delay and prejudice to Plaintiffs, the Court thus should consolidate the preliminary injunction hearing with a prompt trial on the merits, stay Plaintiffs’ remaining claims, immediately

direct the FDA to produce the complete administrative record, and set an expedited schedule for trial.

I. This Court should consolidate the preliminary injunction hearing with the trial on the merits.

To resolve this case quickly and efficiently, the Court should consolidate the preliminary injunction hearing with the trial on the merits under Rule 65(a).

A. This Court should bring this case to a prompt resolution on the merits.

Consolidating the preliminary injunction hearing with a final trial on the merits will avoid needless repetitive rounds of briefing and promote the prompt resolution of this case.

A prompt final judgment is in everyone's interest. Quickly disposing of a case on the merits can help plaintiffs by shortening the period of irreparable harm, can help defendants by minimizing "the potential adverse effect" of interim injunctions, and can help courts by avoiding "having the same evidence presented both at the preliminary injunction stage and later at trial." Wright & Miller, *supra*.

Consolidation can also help avoid burdening the court and the parties with multiple rounds of briefing on the same dispositive legal issues. Assuming that proper notice is given in advance, this approach allows for the expedition of the case while preserving a fair opportunity for each party to raise all of its arguments, evidence, and objections at trial. *Wohlfahrt v. Mem'l Med. Ctr.*, 658 F.2d 416, 418 (5th Cir. 1981).

For three reasons, the practice of consolidation makes particular sense here. *First*, every party agrees that the outcome of this case will have far-reaching consequences for parties and non-parties nationwide, ECF No. 7 at 24–25; ECF No. 19-1 at 2, 25, ECF No. 28 at 38–40, and so everyone benefits from the certainty that

comes from avoiding interim orders and from a prompt final judgment. *Second*, this Court can ensure that, even on an expedited schedule, every party has a full and fair opportunity to present their case, including the opportunity for the FDA to present the full administrative record. *Third*, the preliminary injunction briefing raises many dispositive legal issues, and the parties have already addressed many key documents in the administrative record and the declarations. There is no need to brief the same issues on preliminary injunction motions, motions to dismiss, motions for summary judgment, and motions after trial.

In short, consolidating the preliminary injunction hearing with the trial on the merits will thus avoid needless “repetition and unnecessary delay.” *Dillon v. Bay City Constr. Co.*, 512 F.2d 801, 804 (5th Cir. 1975).

B. This Court should stay Plaintiffs’ other claims.

As part of consolidating the preliminary injunction hearing with the trial on the merits, this Court should hold or stay Plaintiffs’ other claims or sub-claims while the Court proceeds to consider entering a partial final judgment under Rule 54(b) on the legal claims presented in the preliminary injunction motion.

Under Federal Rule of Civil Procedure 54(b), the Court may enter a partial final judgment on only certain claims in a case upon certifying that there is “no just reason for delay” of a partial final judgment on these claims. This Court can rule on the claims in the preliminary injunction motion, without reaching other claims, because there would be no just reason to delay the prompt resolution of so many dispositive claims, particularly when it may be unnecessary to ever reach Plaintiffs’ additional claims.

Any claims not presented in the preliminary injunction motion thus should be stayed until after the resolution of any appeal, while reserving all rights to all

parties. The parties may notify the Court after any appeal, or when and if further litigation is necessary.

II. The Court should expedite the case, direct the FDA to immediately produce the administrative record, and set an early schedule for trial.

Consolidation need not—and should not—significantly extend the time that the FDA’s actions continue to harm Plaintiff medical associations, doctors, and patients. If this Court enters an order consolidating the preliminary injunction hearing with the trial on the merits, the Court therefore should expedite this case by directing the FDA to immediately collect and produce the administrative record and by setting an expedited schedule for trial.

A. The Court should immediately direct the FDA to produce the complete administrative record.

To avoid delay and prejudice to Plaintiffs, this Court should immediately direct the FDA to collect the complete administrative record and produce it within 30 days. The Administrative Procedure Act requires a court to rule based on the complete administrative record before the agency when the decision was made. *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). Production of the administrative record is thus necessary for the consolidation of the preliminary injunction motion with the resolution of the merits. *See Texas v. Biden*, No. 2:21-CV-067-Z, 2021 WL 4552546, at*2 (N.D. Tex. June 7, 2021). And the parties have already attached much of the administrative record to their preliminary injunction filings.

But, in the past, the FDA has sought to avoid disclosing to the public the complete documents surrounding the agency’s decisions about chemical abortion drugs. The FDA’s publicly released decision documents regularly contain significant

redactions of potential important information.¹ Likewise, in response to Freedom of Information Act (FOIA) requests, the FDA has released only highly, and likely improperly, redacted versions of select documents.² To avoid unnecessary delay of the trial, it should be made clear at the outset that the FDA must immediately collect (and presumptively must produce) an unredacted and complete version of the administrative record for this case. *See generally Gulf Coast Rod Reel & Gun Club, Inc. v. U.S. Army Corps of Eng'rs*, No. 3:13-CV-126, 2015 WL 1883522, at *3 (S.D. Tex. April 20, 2015) (discussing circumstances when courts may order supplementation of an incomplete administrative record, such as when the agency omitted relevant evidence or documents).

Redactions may be appropriate for responses to requests for information under FOIA, but the same redactions are not appropriate in an action under the Administrative Procedure Act. After all, a “FOIA production request is an entirely discrete legal concept that bears no relation to the administrative record compiled for a court’s review under the APA.” *Del. Dep’t of Nat. Res. & Env’t Control v. U.S. Army Corp of Eng’rs*, 722 F. Supp. 2d 535, 544 (D. Del. 2010). FOIA has specific, limited exceptions to production but the administrative record under the APA “should include all materials that ‘might have influenced the agency’s decision.’” *La Union del Pueblo Entero v. Fed. Emergency Mgmt. Agency*, 141 F. Supp. 3d 681, 694 (S.D. Tex. 2015) (citation omitted).

¹ *See, e.g.*, App. 517-25, 624-52.

² “The documents linked from this page have been redacted for certain information that is exempt from disclosure under the Freedom of Information Act, 5 U.S.C. sec. 552.” <http://wayback.archive-it.org/7993/20161024033540/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm085168.htm>.

B. The Court should set an expedited schedule for trial.

This Court also should expedite the case and set a prompt schedule for trial.

First, this Court should set a prompt trial date. A bench trial should be held as soon as possible, but no later than two months from the court's consolidation order. An early status conference, followed by a joint pretrial report, is likely the most convenient way to identify the date, basic format, and length for the trial.

Second, this Court should enter a scheduling order setting expedited deadlines for limited supplemental briefing and for any motion practice necessary.

To allow the parties to fully develop their case, supplemental briefing should start immediately, limited to the legal claims presented in the preliminary injunction motion. Supplemental briefing should concern only issues that were not raised in the preliminary injunction motion but that are necessary for ruling on Plaintiffs' request for a partial final judgment. *See Order, Texas v. Biden*, No. 2:21-cv-00067 (N.D. Tex. June 29, 2021), ECF No. 66 (providing for supplemental briefing on legal standards, burdens of proof, and final remedies); *Order, Texas v. Biden*, No. 2:21-cv-00067 (N.D. Tex. July 22, 2021), ECF No. 86 (calling for supplemental briefing on final remedies). Supplemental briefing may be appropriate here, for example, on the legal standard for granting partial final judgment and on the appropriate final relief (e.g., a permanent injunction, vacatur, and a declaratory judgment) but only as to the claims present in the preliminary injunction motion. Plaintiffs' supplemental brief of up to 20 pages should be due 14 days from the Court's order; any supplemental or response briefs from the FDA and Danco Laboratories of the same lengths should be due 14 days later; and Plaintiffs' reply of up to 10 pages should be due 5 days afterward. Each party should also be allowed to submit their proposed final judgment order.

Any motions disputing the inclusion or omission of items from the administrative record, as well as any other motions raising evidentiary disputes,³ should be expedited for decision before trial. These motions should be due within 7 days of the FDA's designation of its final production; any responses should be due 5 days later; and any replies should be due 3 days afterward.

If, after production of the final and complete administrative record, either party needs to file a supplemental brief on how new items in the administrative record bear on the issues in dispute at trial, any further supplemental briefs should be briefed on an expedited schedule for decision before trial.

Third, the Court should direct the parties to draft a joint pretrial report 20 days before trial identifying the parties' preferred format for trial, identifying any stipulations, and identifying the disputed issues of law and fact for trial. A scheduling order at or near trial can set forth appropriate deadlines for the parties to submit their post-trial proposed findings of fact and conclusions of law.

CONCLUSION

This Court should consolidate the preliminary injunction hearing with a trial on the merits under Rule 65(a)(2), stay or hold Plaintiffs' other claims, direct the FDA immediately to collect and produce the complete administrative record, and set an expedited schedule for trial.

³ Plaintiffs do not anticipate discovery on these claims at this time, with the exception of the production of the administrative record.

Respectfully submitted February 10, 2023.

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